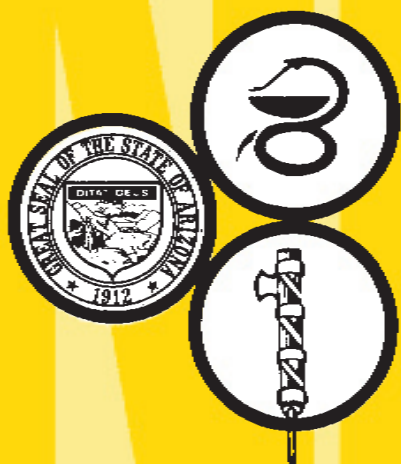


July 2007



Arizona State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

New Pharmacy Board Office Location Information

The Arizona Department of Administration (DOA) has requested the Arizona State Board of Pharmacy to relocate its offices from leased space in a privately owned building to a state-owned facility by July 2, 2007. As many of you are aware, the Board always attempts to comply with requests from other state agencies. In order to accomplish this particular request several significant hurdles were encountered, but we believe that we will have successfully negotiated all of them by the target date. The most significant hurdle was that the space reserved by DOA for the Board is located on the second floor of the Executive Tower located in Room 250 at 1700 West Washington Street, Phoenix, AZ, 85007. Since this space is part of the capitol mall complex, the required security procedures in place are quite significant and may reduce the current easy entry and exit for customers familiar with our Glendale location. The Executive Tower security procedures require every visitor to pass through a metal detector similar to those in use at airports. This makes the office more difficult to access physically, so we have made every effort to implement some of our planned computer online services earlier than originally planned. Online applications for all license and permit applications as well as most associated functions should be available to all of our customers by the planned date of the move. The online services we will provide should reduce or eliminate any deterioration in the quality of the services resulting from the more restrictive access to the new location. The Board also had to invest significant funds to renovate the existing space so that our particular office procedures can continue to be performed at the capitol mall location as efficiently as they have been in the past at the Glendale offices. We have also lost several key employees who did not want to travel the extra distance to the new location. We hope to recruit and train replacements as soon as possible. Another issue we encountered was in obtaining space physically adjacent to the new offices large enough to hold Board meetings. For a time it looked like we would be required to rent private meeting space for each meeting and endure the extra logistical difficulties involved as well as subverting the original purpose for the move, which was a shift away from utilizing private facilities. In the end, DOA personnel did a remarkable job in obtaining suitable space on the third floor of the Executive Tower for this purpose. The space for Board meetings is actually a little larger and more suitable for the meetings than our existing meeting room. The office staff will be providing notice to our existing customers of the new address and telephone numbers before the end of June. Please look for the notice and plan to visit the new facility sometime in July. See you there.

Permissible Duties – Pharmacy Clerks

The Board would like all pharmacy personnel in Arizona to be aware of the limitations on the use of unlicensed pharmacy clerks. During recent Board complaint conferences it seems that many pharmacy personnel are confused about duties of unlicensed clerks versus duties of licensed pharmacy technicians. Clerks may be utilized to perform the following duties:

Cashiering – clerks may act as cashiers on sales of prescriptions and over-the-counter (OTC) products, including determining if the prescription is ready for pick up. In determining a prescription's readiness, a clerk may look in the computer system, but the clerk may not be able to do any processing or make any changes to the computer record and must have completed Health Insurance Portability and Accountability Act training.

Bookkeeping – clerks may keep the pharmacy's books, including documenting third-party reimbursement.

Pricing and stocking – clerks may send and receive orders to replenish the pharmacy's stock, unpack and price the drugs, and place the drugs on the pharmacy's shelves.

Delivering – clerks may deliver a patient's prescription and OTC drug orders to the patient's home.

Telephone – clerks may answer non-professional telephone inquiries, including receiving a refill request. Any refill request received needs to be passed on to a pharmacist, intern, pharmacy technician, or pharmacy technician trainee who can process the refill. Clerks may not initiate or accept refill authorizations or answer any professional questions.

Receiving new written prescriptions – clerks may receive new written prescriptions from a patient but must pass the prescription on to a pharmacist, intern, pharmacy technician, or pharmacy technician trainee who can process the new prescription.

OTC drugs – clerks may help patients find OTC products, but any questions about drugs must be directed to a pharmacist.

Please see the Board Web site at www.azpharmacy.gov under Important Links for a chart comparing duties of pharmacy clerks to technician trainees and certified technicians.

Disciplinary Actions – Board of Pharmacy (Actions since April 2007 Newsletter)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

Pharmacy Board Actions – Pharmacists:

Bach, John (S09345) – License revoked. Effective May 10, 2007.

Daily, Marjorie (S13599) – Revocation of license stayed. Five-year probation with set terms and conditions. Effective April 2, 2007.

Denick, Kevin (S08392) – Pharmacists Assisting Pharmacists of Arizona (PAPA) participation terminated. Effective May 9, 2007.

Kinas, Dana (S13541) – License revoked. Effective March 28, 2007.

Kudish, Stan (S10354) – License suspended six months to one year, followed by four to four-and-a-half years probation. Five year PAPA contract. Effective April 2, 2007.

Malladi, Venkateswara (S12355) – Three years probation with two years psychiatric treatment. Effective May 10, 2007.

Continued on page 4



FDA Issues Guidance on Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of diethylene glycol (DEG) poisoning, Food and Drug Administration (FDA) recently issued a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. The guidance is available on the FDA Web site at www.fda.gov/cder/guidance/7654fnl.htm. FDA is accepting electronic comments on the guidance at www.fda.gov/dockets/ecomments.

Improperly Compounded Colchicine Blamed for Recent Deaths

Compounded colchicine that was 10 times as potent as labeled was responsible for two recent deaths in Oregon and Washington, the *Portland Tribune* reported on April 27, 2007. State officials are investigating the drug's role in a third death, also in Oregon. The drug was sent to a Portland, OR, clinic by ApothéCure, Inc, a Dallas, TX-based compounding pharmacy that distributes its drugs throughout the country. The two patients who died had received injections of colchicine as a treatment for back pain. Lab tests revealed that the colchicine administered in the two deaths had a potency of 4 mg/ml, rather than the 0.5 mg/ml stated on labels. According to Gary A. Schnabel, executive director of the Oregon State Board of Pharmacy, ApothéCure, a licensed Texas pharmacy, may be operating as a manufacturer. Both the Oregon Board and the Texas State Board of Pharmacy have opened investigations into the incident. The Texas Board advised ApothéCure to stop making colchicine; the company agreed, the *Portland Tribune* reported. On May 2, FDA announced the recall of all strengths, sizes, and lots of injectable colchicine compounded and sold by ApothéCure within the last year. The FDA MedWatch Safety summary on this issue is available at www.fda.gov/medwatch/safety/2007/safety07.htm#Colchicine.

New Podcasts Provide Emerging Drug Safety Information

FDA recently supplemented its print- and Web-based public health advisories with the launch of an audio broadcast service providing emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players. The service is part of FDA's ongoing effort to broaden and speed its communications on the safety of marketed medications when unexpected adverse events are reported to FDA. Since FDA launched the service in February 2007, broadcasts have addressed the potential hazards

of local anesthetics used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome; and serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients. The broadcasts are available on the FDA Web site at www.fda.gov/cder/drug/podcast/default.htm.

Prevent Tragedies Caused by Syringe Tip Caps



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Over the past several years, there have been a number of reports where children have swallowed or choked on hypodermic syringe caps that were overlooked by parents and left on the syringes administering the medication. In 2001, a 5-month-old child asphyxiated when a cap from a Becton Dickinson 3 ml hypodermic syringe ejected into his throat during medication administration. In this case, a pediatrician provided the parents with the hypodermic syringe (without the needle) to administer Vantin® (cefepodoxime) suspension. With the cap intact, the father inserted the syringe into the Vantin, pulled back the plunger, and the medication flowed into the syringe. To him, the cap appeared to be part of the syringe. When he placed the syringe containing the medication into the baby's mouth, the cap flew off and became lodged in his airway. The baby was taken to the hospital where a procedure was performed to remove the cap; however, he did not survive.

Despite these reports, the mother of a 9-month-old child recently notified the Institute for Safe Medication Practices about a near fatal experience involving her child. Her community pharmacist gave her a parenteral syringe (without the needle) to help her accurately measure and administer an oral rehydration liquid for her daughter. Unfortunately, the pharmacist's good intention resulted in patient harm. The mother was unaware that the syringe tip held a small, translucent cap; however, despite this, she was able to withdraw the oral liquid. Then as she administered the liquid, the cap on the end of the syringe ejected and became lodged in the child's throat, causing airway obstruction. Fortunately, the child recovered.

Although parenteral syringes are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids without realizing how dangerous this practice may be. Some syringe



manufacturers place the small, translucent caps on parenteral syringes packaged without needles as a protective cover. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal. Subsequently, medications can be drawn into many of these syringes without removing the caps. If not removed before administration, the force of pushing the plunger can eject the cap and cause it to lodge in a child's trachea.

Safe practice recommendations: Consider the following strategies to help protect your patients from tragedies caused by syringe tip caps.

- ◆ **Increase awareness.** Share this and previous errors with staff to illustrate why parenteral syringes should never be used for oral liquid medications. Show staff a video from FDA and ISMP highlighting this issue (access the video link at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=3#6).
- ◆ **Product availability.** Ensure that oral syringes (without caps) or other appropriate measuring devices are readily available for distribution or purchase at your practice site. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep a few different sizes on hand to ensure proper measurement of smaller doses.
- ◆ **Limit access.** If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of this error.
- ◆ **Warning labels.** Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- ◆ **Educate patients and caregivers.** Provide education to patients and caregivers regarding proper use of an oral syringe (or other measuring device). Demonstrate how to measure and administer the dose and inform them about how to clean the device, if it is to be reused. Several years ago, Becton Dickinson voluntarily elected to package parenteral syringes without the small caps in response to this serious issue. However, since some manufacturers still include a cap on parenteral syringes, the danger of asphyxiation with the cap is still present. We have again contacted FDA to alert them about this problem. They have stated that they will be following up with each syringe manufacturer with the goal to get the syringe caps removed. At the very minimum, we believe that the packaging of parenteral syringes should be required to clearly state, "not for oral use" or "not for use with oral liquids."

New FDA Web Page Warns Against Buying Isotretinoin Online

FDA has launched a special Web page to warn consumers about the dangers of buying isotretinoin online. Improperly used, isotretinoin can cause severe side effects, including birth defects and serious mental health problems. The Web page, www.fda.gov/buyonline/accutane, is positioned as a search result on Internet search engines when consumers initiate an online search for the drug under any one of its four names (isotretinoin is sold under the brand name of Accutane® and in generic versions called

Amnesteem™, Claravis™, and Sotret®). The Web page warns that the drug "should only be taken under the close supervision" of a physician and a pharmacist, and provides links to related information, including ways to check that drugs purchased online come from legitimate pharmacies.

To reduce risks, FDA and the manufacturers of isotretinoin have implemented a strict distribution program called iPLEDGE to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin. Isotretinoin is available only at pharmacies that are registered for this distribution program. Additionally, the distribution program is designed to prevent the sale of isotretinoin over the Internet. Dispensing must comply with the agency's risk management requirements.

Tampering Results in Misbranding of Ziagen as Combivir

GlaxoSmithKline and FDA warned health care professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen® as Combivir® and employed counterfeit labels for Combivir tablets. Two 60-count misbranded bottles of Combivir tablets contained 300 mg tablets of Ziagen.

The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California.

Pharmacists are advised to immediately examine the contents of each bottle of Combivir in their pharmacies to confirm that the bottles contain the correct medication. If a bottle contains anything other than Combivir tablets, pharmacists are advised to notify the manufacturer.

The letter from GlaxoSmithKline and FDA, containing photos of actual Combivir and Ziagen tablets, is posted on the FDA Web site at www.fda.gov/medwatch/safety/2007/Ziagen_Dear_RPh_03-29-2007.pdf.

FDA Issues Halt on Manufacture, Distribution of Unapproved Suppository Drugs

FDA notified health care professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

These products, used to treat nausea and vomiting in adults and children, have been marketed under various names, including Tigan®, Tebamide™, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA.

FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their health care professionals. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms.

The MedWatch safety summary and a link to the full press release are available at www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide.

Massrock, Peter (S12166) – Probation terminated. Effective May 9, 2007.

Okamoto, Paul (S05482) – Probation terminated. Effective May 9, 2007.

Rosch, Judith (S08544) – License suspended six months to one year, followed by four to four-and-a-half years probation. Effective May 10, 2007.

Soni, Bhavesh (S13212) – Probation terminated. Effective May 9, 2007.

Sanchez, Paul (S11492) – Probation terminated. Effective March 29, 2007.

Walden, Josh (S14299) – Voluntary Surrender. Effective April 2, 2007.

Pharmacy Board Actions – Technicians:

Accetta, Karen (T09196) – License revoked. Effective May 10, 2007.

Begay, Caroline (T00657) – Probation terminated. Effective May 9, 2007.

Kesterson, Eric (T01752) – Revocation of license stayed and placed on two-year probation with set terms and conditions. Effective May 10, 2007.

Simmons, Randy (T00598) – One-year probation with \$250 fine and eight continuing education. Effective April 2, 2007.

Torda, Catherine (T00002) – Revocation of license stayed and placed on two-year probation with set terms and conditions. Effective May 10, 2007.

Velazquez, Dione (T08567) – License reinstated with one-year probation. Effective May 10, 2007.

Disciplinary Actions – Other Boards:

Medical Board

Baez, Le Roi A. (MD 30154) – *Interim Finding of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona, is summarily suspended pending a formal hearing. Effective March 26, 2007.

Berg, Gary L. (MD 21112) – Respondent shall not practice clinical or administrative medicine or any medicine involving direct patient care and is prohibited from prescribing any form of treatment including prescription medications until applying for and receiving Board approval. Effective March 17, 2007.

Cooper, Grant Wayne (RN 094171 and AP 0851) – Respondent's license is summarily suspended pending a formal hearing. Effective March 28, 2007.

Everly, Shelley (MD 28385) – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until Respondent applies to the Board and receives permission to do so. Effective April 24, 2007.

Foley, Nils E. (MD 32906) – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until Respondent applies to the Board and receives permission to do so. Effective February 9, 2007.

Gaul, William V. (MD 13119) – License revoked. Effective April 17, 2007.

Gibbs, Marvin L. (MD 13736) – *Interim Finding of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective April 19, 2007.

Grade, Thomas J. (MD 10424) – *Interim Finding of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective May 18, 2007.

Grams, Mark L. (MD 11869) – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until Respondent applies to the Board and receives permission to do so. Effective January 11, 2007.

Kohout, Melanie K. (MD 23105) – License surrendered to the Board. Effective April 12, 2007.

Koppula, Sampurnarao (MD 13707) – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until Respondent applies to the Board and received permission to do so. Effective March 9, 2007.

Leung, King T. (MD 10262) – License revoked. Effective April 13, 2007.

Mastrin, Marcia A. (MD 31029) – Respondent issued a Decree of Censure. Effective February 9, 2007.

McGlamery, James A. (MD 10971) – *Interim Consent Agreement* – Respondent's practice is restricted in that he shall not work more than 40 hours per week for six months from effective date of consent. Respondent's practice shall be supervised by a Board-staff approved physician from his group practice. At the conclusion of the six months the supervising physician will report to the Board regarding recommendation of allowing the Respondent to resume full practice. Effective February 13, 2007.

Miller, Eric J. (MD 19279) – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until Respondent applies to the Board and receives permission to do so. Effective January 4, 2007.

Miranda, Christina (PA 3338) – License surrendered to the Board. Effective February 28, 2007.

Morgan, John C. (MD 25871) – Respondent is issued a Letter of Reprimand. Respondent is placed on probation for five years with set terms and conditions. Effective February 9, 2007.

Normann, Peter James (MD 33254) – *Interim Consent Agreement* – Respondent shall not perform any office procedures, surgeries or use of conscious sedation until further Order of the Board. Effective May 3, 2007.

O'Beirne, Edward N. (PA 1911) – License surrendered to the Board. Effective May 16, 2007.

Sameshima, James L. (MD 24707) – Respondent issued a Letter of Reprimand. Effective February 9, 2007.

Stassen, Denise (PA 2742) – License revoked. Effective March 1, 2007.

Tolman, Kenneth James (MD 36900) – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until Respondent applies to the Board and receives permission to do so. Effective May 7, 2007.

Trejos, Franklin A. (PA 3137) – License revoked. Effective March 1, 2007.

Underwood, Kenneth L. (PA 1934) – License revoked. Effective March 1, 2007.

Wilkinson, Malcolm G. (MD 21001) – *Interim Consent Agreement* – Respondent shall not perform general surgery until he applies to the Board and receives permission to do so. Respondent may continue to perform minor surgical procedures in his office using local anesthesia. Effective February 1, 2007.